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4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1243]

Prospective Grant of an Exclusive Patent License: A Diagnostic Tool Based Upon Magnetic Resonance Spectroscopy Pre-Processing and Renormalization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is contemplating the grant of an Exclusive Patent License to practice the invention embodied in the U.S. Patent listed in the SUPPLEMENTARY INFORMATION section of this notice to Voxel Systems, LLC located in Houston, Texas.

DATES: Only written comments and/or applications for a license that are received by FDA's Technology Transfer Office on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE *FEDERAL REGISTER*], will be considered.

ADDRESSES: Inquiries and comments relating to the contemplated Exclusive Patent License should be directed to: Ken Millburne, Food and Drug Administration Technology Transfer Office, Bldg. 1, Rm. 4213, Silver Spring, MD 20993, 240-478-1662; email: Kenneth.Millburne@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

FDA Reference No.: E-2009-011/US-04: "System for Magnetic Resonance Spectroscopy of Brain Tissue for Pattern-Based Diagnostics"

I. U.S. Non-Provisional Application 13/509,539, filed November 12, 2010 (FDA Reference No.: E-2009-011/US-04).

II. U.S. Patent granted November 4, 2014: U.S. Patent 8,880,354 B2 (FDA Reference No.

E-2009-011/US-04)

The patent rights in this invention have been assigned to the Government of the United States of America.

The prospective exclusive license territory may be worldwide and in fields of use that may be limited to: (1) any and all in vivo use, application, or developmental activity related to the software, processing algorithm, and Licensed Processes and Products; (2) all human and animal diagnostics, in pre-clinical, or clinical utilizations for any and all maladies; (3) all human research applications for expanded magnetic resonance imaging (MRI) utilization, application development, drug development tools, molecular compound characterization, algorithms, and biomarker identification and development; and (4) all animal or other research applications and translational studies for ultra high-field MRI investigations, drug development, metabolite, and biomarker identification.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing. The prospective exclusive license may be granted unless, within 15 days from the date of this published notice, FDA receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated December 27, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021-28397 Filed: 12/30/2021 8:45 am; Publication Date: 1/3/2022]